

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MARYDILYS ANDERSON
WOLF, GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 19 JUL 2005	
FOR FURTHER ACTION See paragraph 2 below	
Applicant's or agent's file reference H0498.70215	
International application No. PCT/US04/40977	International filing date (day/month/year) 08 December 2004 (08.12.2004)
Priority date (day/month/year) 08 December 2003 (08.12.2003)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): C12N 5/00 and US Cl.: 435/371, 366, 325	
Applicant PRESIDENT AND FELLOWS OF HARVARD COLLEGE	

DOCKETED
JUL 22 2005

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Confirmation ☐
Docketing ☒

Initials

10/19/05

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <div style="text-align: center;"> Leon Lankford </div> Telephone No. 571-272-1600
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/40977

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>2-14, 16-17, 20-33 & 35-50</u>	YES
	Claims <u>1, 15, 18, 19 & 34</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-50</u>	NO
Industrial applicability (IA)	Claims <u>1-50</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1, 15, 18-19 & 34 lack novelty under PCT Article 33(2) as being anticipated by Bagutti et al.

Bagutti teaches populations of keratinocytes which are differentiated from embryonic stem cells. The use of an intermediate "nodule" is taught. The reference anticipates the claim subject matter.

Claims 1-50 lack an inventive step under PCT Article 33(3) as being obvious over Bagutti et al.

Bagutti teaches populations of keratinocytes which are differentiated from embryonic stem cells. The use of an intermediate "nodule" is taught. The reference is silent on the specific culture conditions currently claimed however the method claimed would have been obvious to a routineer in the art because Bagutti teaches the differentiating of ES cells into keratinocytes and the factors required to do so. The claimed invention lacks an inventive step because the routineer in the art would have found it obvious to optimize the method of Bagutti to best produce pure cultures of keratinocytes.

Claims 1-50 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.